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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,518	11/16/2001	William Fenical	6627-PA1022	7755

7590 02/15/2005  
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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/991,518

**Applicant(s)**

FENICAL ET AL.

**Examiner**

Irene Marx

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,13,17,18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,13,17,18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/30/04 & 11/15/04
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed 12/2/04 is acknowledged. Claims 1, 13-18 and 20 are being considered on the merits.

#### ***Claim Rejections - 35 USC § 112***

Claims 1, 13, and 17-18 and 20 are/remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of marine Actinomycetes of the genus *Salinospora*, which comprise certain “signature nucleotides” at certain positions based on “a sequence of *E. coli* 16S rRNA” “as numbered by using the Ribosomal Project alignment”. However, there is nothing on the instant record to establish that a sequence of 16S rRNA of *E. coli* and the indicated positions are invariant and are the sole and conventional numbering system for sequences of 16S rRNA of Actinomycetes. The Mincer *et al.*, Cole *et al.* and Lane *et al.* papers are all directed to phylogenetic analyses using the project. However, there is no specific guidance regarding the unequivocal identification of strains, as required in the instant case, wherein a genus of bacteria is claimed which admittedly has about 98% sequence similarity with *Micromonospora olivasterospora* (Specification, page 11).

That sequences are conserved does not necessarily mean that entries in the “Ribosomal Database Project” are permanent and invariant or that the *E. coli* sequences have not been or will not be subject to revisions, such as revisions in the numbering system. The significance of the choice of nucleotides 27-1492 of *E. coli* is not readily apparent.

#### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that certain sequences from three strains CNH643, CNH646, CNH898 are deposited at Genbank, but applicant did not respond to the query whether any of the *Salinospora* strains isolated are freely available to the public for comparison purposes and for

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cultivation to produce biomolecules, for example. The specification only provides guidance for the identification of strains by obligate salt requirement and "signature nucleotides".

No objective evidence has been provided on this record to demonstrate the invariance of the "*E. coli* numbering system" in the cited Database. On the contrary, in the response filed 5/24/04, applicants indicate that "a reference sequence of *E. coli* can be chosen from the Ribosomal Database Project (RDP)" (Page 7, paragraph 1). It cannot be readily assessed how "a reference sequence of *E. coli*" differs from any other "reference sequence" or how one "reference sequence" is to be selected for purposes of the claimed invention.

Therefore the rejection is deemed proper and it is adhered to.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 13-18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 13 are vague and indefinite in the recitation of certain positions in the 16S rRNA with an indication of the context of these positions based on positions in the *E. coli* numbering system in "Ribosomal Database Project". That applicants have aligned the rRNA of *E. coli* with that of *Salinospora* strains at some point does not unequivocally establish the position intended by 207, 366, 467, etc.. Similarly, that sequences are conserved does not necessarily mean that entries in the "Ribosomal Database Project" are permanent and invariant or that the *E. coli* sequence has not been or will not be subject to revisions. The significance of the choice of nucleotides 27-1492 of *E. coli* is not readily apparent.

There is nothing on this record to demonstrate invariance of the "*E. coli* numbering system" in the cited Database. On the contrary, in the response filed 5/24/04, applicants indicate that "a reference sequence of *E. coli* can be chosen from the Ribosomal Database Project (RDP)" (Page 7, paragraph 1). It cannot be readily assessed how "a reference sequence of *E. coli*" is to be chosen for purposes of the claimed invention.

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Revisions or updates to database entries, including, of course, to various reference *E. coli* sequences can be made at any time. The interpretation of a claim that refers to a database entry is dependent upon the particular revision, update or release date of that particular entry.

It is recommended that the "signature nucleotides" in claim 1 be correlated specifically to SEQ ID NO: 3, 4 and 5 as recited in claims 14-16.

To clarify the invention and for the sake of consistency, it is recommended that claim 18 be amended to state that a strain belonging to the genus *Salinospora* is cultured in a culture medium containing NaCl to account for the obligate requirement of sodium for growth.

Thus the strains intended are not properly identified and the invention is not particularly pointed out and distinctly claimed.

#### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's argue that one of ordinary skill in the art would understand the claim as written. Yet there is no assurance in the instant record to show or suggest that the *E. coli* sequence as depicted in the cited Lane paper (1985), for example, has not been subject to revisions in the cited database during that time, that might affect the precision of the numbering system.

The metes and bounds of the claim(s) are not clearly set forth.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
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